

REMARKS

The Office Action has allowed Claims 10-20, 25, 39 and 40. However, it has rejected Claims 1-9, 21, 22, 26-38 and 41-52 under 35 U.S.C. §102(b) as defining subject matter which is allegedly anticipated by, or in the alternative under 35 U.S.C. §103(c) as allegedly defining subject matter which is rendered obvious by the teachings in WO 92/16545, of which Heikkila, et al. are the inventors ("Heikkila, et al.").

Applicants are enclosing a Declaration under 37 C.F.R. §1.132 by Juha Nurmi, one of the inventors of the above-identified application, which, when considered with the comments hereinbelow are deemed to place the present application in condition for allowance. Favorable action is respectfully requested.

The Office Action has indicated that Claims 10-20, 25, 39-40 are allowed. Applicants are willing to permit the application to issue even without the product claims. Nevertheless, the applicants respectfully submit that for the reasons given herein the remaining rejected claims are allowable.

The rejected subject matter of the present invention is directed to, inter alia, β -lactitol, and the use thereof and compositions containing same.

Pursuant to the rejection of Claims 1-9, 21, 22, 26-38 and 41-52 under 35 U.S.C. §102 or in the alternative under 35 U.S.C. §103, the Office Action cites Heikkila, et al.

The Office Action alleges that Heikkila, et al. teach crystalline anhydrous lactitol further alleging that it is not "seen where Heikkila, et al. exclude the β -lactitol" (sic). Page 3 of Response.

Contrary to the allegations of the Office Action, Heikkila, et al. disclose lactitol α crystals and do not teach, disclose or suggest any β -lactitols, as presently claimed or compositions of matter containing same, as claimed.

In support thereof, applicants are filing concomitantly herewith a Declaration under 35 U.S.C. §1.132 of Juha Nurmi ("Declaration"). Attention is directed to Paragraphs 8, and 21 of the Declaration, wherein Nurmi testifies that Heikkila, et al. are not only directed to α -lactitol but that the teachings therein are limited to α -lactitol and its use, and that there is no discussion or suggested therein of a product containing β -lactitol.

More specifically, contrary to the allegations in the Office Action, the process described in Heikkila, et al. cannot make any β -lactitol. Attention in this regard is directed to Paragraph 11 of the Declaration wherein Nurmi testifies that he repeated the process described in Heikkila, et al. and found that the product thereof was α -lactitol, and did not contain any β -lactitol, as verified by x-ray diffraction. As further testified by Nurmi, x-ray diffraction is a very sensitive technique, and if any β -lactitol were formed, it would have been detected the formation of α -lactitol. Id. As Nurmi testifies, "...when the product of the process described in the Heikkila, et al. (reference) was subjected to x-ray diffraction, the x-ray diffraction pattern revealed no β -lactitol formation." Id. Moreover, as described in the underlying application and in Paragraphs 14 and 15 of the Declaration, the β -lactitols are prepared from the α -lactitols by subjecting the latter to specific conditions. These various conditions for making the β -lactitols were not described in Heikkila, et al. For example, the inventors found that the α -lactitol crystals would transform to the β -lactitol only in the wet state, provided that the crystallized α -crystals were retained in the mother liquor at a constant temperature between 100° and 70°C. Paragraph 14 of Declaration. The process is very slow, as testified by Nurmi. Id. More specifically, the

amount of time for the transformation took several hours to several weeks. Id. A review of Heikkila, et al. readily reveals that it did not teach or suggest maintaining a crystal mass in the mother liquor for any prolonged time, at an elevated temperature.

Other methods for making the β lactitols were also not described in Heikkila, et al. See Paragraph 15 of Declaration. For example, another method to convert α lactitol into β lactitol occurred under very slow crystallization procedures “wherein the supersaturation of the solution in α -lactitol was close to zero and the crystals formed very slowly and removed in solution for prolonged period of time”. Id. Again a review of Heikkila, et al. reveals that this process was not described in Heikkila, et al. Further, another method of preparing β -lactitol is by seeding with β -lactitols, which process was not described in Heikkila et al. (See Paragraph 16 of Declaration).

Thus, since Heikkila, et al. did not teach, disclose or suggest these processes, consistent with the x-ray diffraction data. Heikkila, et al. do not teach or disclose a process for making β -lactitol.

Thus, contrary to the allegations in the Office Action, β -lactitol is necessarily excluded from the teachings in Heikkila, et al. This is evidenced by the failure of Heikkila, et al. to teach or suggest any method to make β -lactitol. In addition, as evidenced by the x-ray diffraction pattern, a very sensitive technique, the product formed from the process taught in Heikkila, et al. revealed only the formation of α lactitol; no β -lactitol product was detected. Thus, the β lactitol form cannot be inherently prepared by the process described in Heikkila, et al.

As shown in the application and testified by Nurmi, the α form is quite different from the β -form. Attention is directed to Page 8 of the instant specification, and Paragraph 10 of

the Declaration which compares the α and β lactitols. As clearly shown by the data in Table 1 of the application and Paragraph 10 of the Declaration, the α and β forms have different crystal forms, the α -lactitol form being monoclinic, while the β form is orthorhombic. Moreover, they have different spatial groups, the α lactitol has the spatial group $P2_1$ while the β lactitol has the spatial group $P2_12_12_1$. Id. Moreover, the β -lactitol has different unit cell parameters than the α -lactitol. Id. As described in the underlying application, and in Paragraph 10 of the Declaration the unit cell parameters of the β crystal form of lactitol are as follows: a is about 9.69 Å, b is about 11.1 Å and c is about 14.0 Å. On the other hand, the parameters for the α -crystal is a = 7.614 Å, b = 10.757 and c = 9.370 Å, as disclosed in Heikkila, et al. on Page 4, lines 3-7 thereof. Id. Thus, there is no question that the α lactitol is different from β lactitol. Moreover, these characteristics identifying the β -lactitol are recited in Claims 1 and 6 and 21; as clearly seen by the data in Heikkila, et al. these parameters are not characteristics of the α -lactitol.

Further, these characteristics recited therein are not applicable to any other lactitol that is known. See Paragraphs 12 and 13 of Nurmi Declaration. Thus, Claims 1, 6, 21, 26, 33 and 34 and claims dependent are directed to subject matter not contemplated by Heikkila, et al.

Moreover, as shown by the underlying specification, and testified by Nurmi in Paragraph 13, the β crystals have different properties than the α lactitols. For example, the β crystals are harder than the α crystals. Further, they have different melting enthalpies with the α form being 149 J/g, while the β form is 166-169 J/g. Moreover, as indicated in the specification, and in the Declaration in Paragraphs 10, 17 and 18, the α and β forms can be easily distinguished in the x-ray powder diffraction as a result of the different structures. Thus, the α form prepared by the teachings of Heikkila, et al. is not the same as the β form. Furthermore, compositions of matter containing the β form are not the same as compositions of matter containing the α form.

Thus, Heikkila, et al. do not teach or disclose β lactitols or compositions containing same, as claimed.

Furthermore, these different crystal forms translate into different characteristics, e.g., different morphology, heats of fusion, solubility, hygroscopicity and hardness. These different physical properties manifest themselves into different characteristics exhibited by the β -lactitol crystals relative to the α -crystals. These different properties are unexpected and provide unexpected advantages of the β -lactitol relative to the α -lactitol. See Paragraphs 17-20 of the Declaration. For instance, as described on Page 8 of the instant specification, the β lactitol crystals are very stable and they are harder than the α lactitol crystals. This gives technical advantages to products containing β lactitol, e.g. in foodstuffs, chocolates and toothpastes relative to the corresponding products containing α lactitol. For example, both anhydrous lactitols are non-hygroscopic, but the β lactitol absorbs water even more slowly than does the α lactitol. See Paragraph 18 of Declaration. This makes the β lactitol even more stable than the α lactitol at storage in moist and warm conditions, thereby making products containing the β lactitol more stable than similar products containing α -lactitols in lieu of the β -lactitol. Id. The β lactitol has a lower solubility at higher temperatures than the α lactitol. Id. This affects the way the two lactitol forms dissolve in liquids during use and processing. Id. The melting enthalpy of the β lactitol is higher than that of the α lactitol, which means that the former requires more heat to melt or, in other words, it remains a solid for a longer time without melting. Id. Thus, a composition of matter containing β lactitols are not only different, but also exhibit unexpected advantages over the corresponding composition of matter containing α lactitol. See Paragraphs 17-20 of Declaration.

In addition, the differences between the two lactitol forms described hereinabove are more marked at high temperatures and in moist conditions, which further adds to additional improvements and unexpected properties in foods, confectionaries, and toothpaste containing β lactitol relative to those containing α lactitol. See Paragraphs 19 and 20 of Nurmi Declaration.

Consequently, since the β lactitol as such is new and inventive, also its uses and compositions of matter containing same are new and are not suggested in the cited reference. Further, the improved stability, hardness, solubility and improved non-hygroscopicity of the β lactitol relative to the α lactitol are totally unexpected and this makes the compositions of matter and the use thereof in various applications inventive over the prior art use of α lactitol. See Paragraphs 17-20 of Declaration.

Moreover, as indicated hereinabove, Heikkila, et al. do not teach or suggest any β lactitol, nor is any β lactitol inherently prepared by the teachings therein. Thus, Heikkila, et al. is not enabling for making the β lactitol or products containing same. More importantly, the teachings therein not only do not place the β lactitol into the hands of the public. Furthermore, since Heikkila, et al. do not teach, disclose or suggest any β lactitol, based upon the teaching in the cited reference, it is quite surprising that a lactitol can exist in the β form in the first instance. Based upon the teachings therein there is no expectation by one of ordinary skill in the art of the existence of the β form. Thus, for another reason the rejected claims are patentable over the prior art.

Furthermore, even if some α -lactitol is present with the β -lactitol, the prior art does not teach, disclose or suggest any composition containing any β -lactitols or any mixture of α lactitols and β lactitols.


Since Heikkila, et al. do not teach, disclose or suggest β lactitols or the

unexpected advantages of β lactitols relative to α lactitols or the products containing β lactitols, Heikkila et al. cannot render obvious the claims subject matter. Thus, for the reasons provided the rejection of the product claims under 35 U.S.C. §103 is obviated; withdrawal thereof is respectfully requested.

Moreover, applicants respectfully submit that Claim 38 is allowable and that its rejection is in error. It is a process claim dependent upon Claim 15 which is been indicated to be allowed. A claim dependent upon an allowed claim is considered allowable. Moreover, as described hereinabove, and in more detail in the previous response, the contents of which are incorporated by reference, the subject matter in Claims 15 and 38 is not described, taught or suggested by the cited art.

Thus, in view of the Declaration and remarks herein, it is respectfully submitted that the present case is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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